



~~PATENT~~
~~F-5366~~

Attorney Docket No. F-5366

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
Washington, D.C. 20231

APPEAL BRIEF

Dear Sir:

(1) REAL PARTY IN INTEREST

The real party in interest in this appeal is Baxter International Inc., assignee of the invention claimed in the present application, which assignment was recorded in the United States Patent and Trademark Office on or around February 5, 1999.

(2) RELATED APPEALS AND INTERFERENCES

None.

(3) STATUS OF CLAIMS

Claims 1-45 are cancelled. Applicants are appealing the rejection of pending claims 46-66.

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(4) STATUS OF AMENDMENTS

An amendment after final rejection is being separately filed with this appeal brief and is being submitted to overcome the rejections in the final rejection of July 31, 2001, namely, (1) the rejection under 35 USC 112, first paragraph, as to Claims 48-50 and 58-60 and (2) the rejection under 35 USC 112, second paragraph, as to Claims 48-65. The amendment is believed to conform with the requirements of 37 CFR 1.116.

With respect to the rejection under Section 112, first paragraph of Claims 48-50 and 58-60, the Examiner contended that is not clear how applicants' claimed composite sheet membrane can be comprised of both a "flat sheet" and a "contoured", "rippled", and "pleated" sheet.

With respect to the rejection under Section 112, second paragraph, the Examiner rejected the following claims: (1) Claims 46 and 56 for the use of the word "near" as being indefinite; (2) Claim 61 for the recitation of "said skin" as lacking sufficient antecedent basis; and (3) Claims 48-50 and 58-60 as confusing as to how the membrane can includes both a "flat" sheet and a "contoured", "rippled", or "pleated" sheet.

Applicants' separately submitted amendment is believed to address all of the Examiner's Section 112 rejections without necessitating any further examination.

(5) SUMMARY OF INVENTION

This invention is generally directed to a composite sheet membrane with particulate matter substantially immobilized therein.

More specifically, the invention is directed to a flexible, composite sheet membrane 10 comprising a flat sheet polymeric support 18 having a first side and a second side (specification page 12, lines 1-4). Each side comprises a coating of a non-fiberized polymeric material (specification page 12, lines 24-27). The material comprises a particulate (shown as specs in Figs. 3 and 4) blended with a polymer, wherein the particulate is substantially physically immobilized by the polymer. Each of the first and second sides has a coating of the material substantially equal in thickness (specification page 17, lines 14-27).

The outer surface of the membrane has a porous and selectively permeable skin 19 (specification page 12, lines 4-8). Less of the particulate is disposed at or near the outer surface than is disposed further in the interior of the membrane (specification page 16, lines 23-36).

In another aspect of this invention, the flexible, composite sheet membrane 10 comprises a polymeric support 18 which comprises a first side and a second side where at least one of the first and second sides comprises a first coating of a particulate blended with a polymer, wherein the particulate is substantially physically immobilized by the polymer (specification page 18, lines 7-10).

The membrane further comprises a second coating of a hydrophilizing agent (specification page 19, lines 5-13).

In a further aspect of the invention, the membrane 10 comprises a polymeric support 18, a first coating of the non-fiberized polymeric material, and a selectively permeable and porous skin 19 on the outer surface of the membrane (specification page 12, lines 1-8). The membrane is formed in part by introducing the support 18 into a chamber 24 which includes the polymeric material (specification page 16, lines 12-26). The chamber 24 includes a wide opening and a pair of converging walls 43 terminating in a narrow passageway 41 of a predetermined length and an exit gap 40 (specification page 16, lines 16-25). The support 18 is passed through the chamber 24 at the rate of approximately 1-4 ft/min (specification page 22, lines 2-7).

(6) ISSUES

(A) Whether Claims 46-49 and 52-55 and 66 are anticipated under 35 USC 102(b) by U.S. Patent No. 4,728,432 to Sugiyama et al.

(B) Whether Claims 56-59 and 61-62 are anticipated under 35 USC 102(e) by U.S. Patent No. 5,914,039 to Mahendran et al.

(C) Whether Claims 51, 56-59 and 61-65 are obvious under 35 USC 103(a) over Sugiyama et al. in view of U.S. Patent No. 4,384,954 to Nakashima et al.

(7) GROUPING OF CLAIMS

Claims 46-66 do not stand or fall together. Claim 46 and its dependent claims 47-55 stand or fall together. Claim 56 and its

dependent claims 57-65 stand or fall together. Claim 66 is independently patentable.

(8) ARGUMENT

(A) Whether Claims 46-49 and 52-55 and 66 are anticipated under 35 USC 102(b) by U.S. Patent No. 4,728,432 to Sugiyama et al.

Independent Claim 46 is directed to a flexible flat sheet composite sheet membrane that includes a polymeric support having a first side and a second side. Each of the first and second sides includes a coating of a non-fiberized polymeric material. The polymeric material includes a particulate blended with a polymer, with the particulate being substantially physically immobilized by the polymer. In the membrane of Claim 46, each of the sides has a coating of the material that is substantially equal in thickness. The outer surface of the membrane is a porous and selectively permeable skin. Less particulate is disposed near the outer surface than is disposed further in the interior of the membrane.

In the Final Office Action of July 31, 2001, Claims 46-49, 52-55 and 66 were rejected under 35 USC 102(b) as anticipated by Sugiyama et al. On page 4, of the Office Action, the Examiner stated:

Claims 46-49, 52-53 and 66 are rejected under 35 USC 102(b) as being anticipated by Sugiyama et al. (US 4,728,432). Sugiyama et al. [432] discloses a composite membrane comprising particulates contained in a non-fibrous matrix having skin layer (see column 3, lines 29-56; "skin" or surfaces are formed when "prepared by a known method of producing porous membranes...[such as] flowcasting, dipping, coating..."), said non-fibrous matrix being deposited in equal amounts upon a flat sheet

support (column 2, lines 49-51), as recited in instant claim 46. Sugiyama et al. [432] also discloses: 20 micron particles (column 2, lines 47-48), as recited in instant claim 47; the use of contoured/rippled sheets (column 2, lines 49-56), as recited in instant claims 48-49; polyurethane (column 3, line 47), as recited in instant claim 52; 70% particulate and 30% polymer (column 3, line 53), as recited in instant claims 53-54; and polyester mesh supports (column 3, line 14-28), as recited in instant claim 55.

According to the Patent Office (as set forth on page 4-5 of the final Office Action), the formation of a skin layer such as the claimed skin as recited in Claim 46, was considered to be inherent from the teachings of Sugiyama et al.:

As stated within previous Office Actions, and uncontested to date, the formation of a "skin" layer is deemed to be inherent, as activated carbon (or other "sorbents") would be wetted by polymer solutions, thus surrounding said particles with polymer; at the outer edge of the membrane, the thus wetted sorbents would form an outer "skin" layer of polymer separating the particulates from the outside of the membrane. Also see column 3, line 66 to column 4, line 4 of '432, which indicates that particles are contained firmly within the matrix, unless the matrix is made so thin that it cannot firmly surround the particle.

According to the Patent Office, "many of the coating methods within genuses suggested by Sugiyama et al. involve shear forces (example, extrusion, knife coating, continuous web dip coating) also providing for the formation of a skin region" (emphasis added). The "genuses" are presumably the methods generally disclosed in Sugiyama et al., such as "flowcasting, dipping, coating, spraying" (Col. 3, lines 35-36).

Applicants respectfully submit that Sugiyama et al.'s disclosure of these "genuses" cannot, however, anticipate the

membrane of Claim 46 (and/or the method by which it is made). It is well settled that disclosure of a genus does not necessarily disclose every species. In Corning Glass Works v. Sumitomo Electric U.S.A., Inc., 9 USPQ 2d 1962, 1970 (Fed. Cir., 1989), the patent challenger asserted that a claim to a genus would inherently disclose all species. The Federal Circuit rejected the challenger's argument as "wholly meritless whether considered under §102(b) or under 35 USC §103..." Id.

"Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." Hansgirg v. Kemmer, 40 USPQ 665, 667 (CCPA 1939). "Absent the showing of some reasonable certainty of inherency, the rejection...under 35 USC §102 must fail." In re Brink, 164 USPQ 247, 249 (CCPA 1970). "Anticipation of inventions set forth in product claims cannot be predicated on mere conjecture, respecting the characteristics of products that might result from the practices of processes disclosed in references." W.L. Gore & Associates v. Garlock, Inc., 220 USPQ 303, 314 (Fed. Cir., 1983).

In the final Office Action of July 31, 2001, the Patent Office responded by stating that Applicant's arguments are not convincing, "as applicant has not established that a redistribution of particles occurs within the instant invention owing to use of a particular production process" and the Examiner repeated that "the formation of a 'skin' layer is deemed inherent." In doing so, the

Patent Office shifted the burden of proof to the Applicant to show that the prior art references do not support inherency, citing MPEP 2112, ("Once a reference teaching product appearing to be substantially identical is made the basis of a rejection and the Examiner presents evidence or reasoning tending to show inherency, the burden shifts to applicant to show an unobvious difference.")

This reasoning overlooks the requirement that in order to establish inherency "the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex Parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. 1990) (emphasis in original). Sugiyama et al. do not provide a working example that would result in a membrane with a particle distribution as described and claimed in the present application. The disclosed coating methods of Sugiyama et al., at best, disclose a general invitation to produce a membrane having a skin but do not disclose a membrane having the claimed particle distribution characteristics recited in Claim 46.

Inherency is further contradicted by the Declaration of Dr. Sternberg which was also submitted with Applicant's May 7, 2001 Amendment, a copy of which is attached hereto as Exhibit A. The Declaration stated that the processes actually disclosed in Sugiyama et al. would not, by necessity, result in a membrane with a particle distribution as described and claimed in the present application. As stated in the Declaration, without knowing more

about the specifics of the disclosed methods, one of skill in the art would not assume that the techniques described in Sugiyama et al., would result in such a particle distribution. In short, Sugiyama et al. do not expressly or inherently disclose a membrane of the type recited in Claim 46.

In the final Office Action, the Patent Office stated that the Declaration was insufficient because:

[I]t refer(s) only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims.

On the contrary, the Declaration refers to the claimed subject matter of both Claims 46 and 66 even though these claims are not specifically identified by number. In paragraph 4, "the present application discloses and claims a flexible, composite sheet membrane...[which], in one example, is made from a polymer and a particulate dispersed within the polymer...[and] has a porous, outer skin over the membrane interior ...less of the particulate is present near the area of the outer skin than is present further into the interior of the membrane." This language refers to Claim 46. It is also noted that the additional claimed subject matter of Claim 66 is recited in paragraph 5 of the Declaration as this paragraph includes the claimed "chamber" and recites the features, namely, a pair of converging or "V-shaped" walls, and "a narrow passageway" or "gap" of "predetermined length".

The Declaration further supports Applicant's position that Sugiyama et al. fail to support any inherent teaching regarding the formation of a 'skin' layer on the outer surface and the desired particle distribution of the claimed membrane. Despite the Patent Office's contention to the contrary, Sugiyama et al. provide only a vague and generalized invitation that the membrane can be prepared "by the known method of producing porous membranes" including taking a polymer solution containing the absorbent dispersed therein and applying to the support "by means of flowcasting, dipping, coating, or spraying" (Col. 3, lines 29-45).

No structure or apparatus is described or disclosed in Sugiyama et al. for applying the blend onto the support using any of these methods. So, the mere mention of these methods cannot by themselves support the basis required for a conclusion of inherency without knowing more about the specifics of the methods and the apparatus, which is not disclosed or suggested in Sugiyama et al.

Finally, according to the Patent Office, the Declaration does not provide any objective evidence "that the product as produced by the process of [Sugiyama et al.] '432 necessarily contains a difference produced by the claimed process." The final Office Action focuses on the use of the term "may" on page 16 of the specification in order to support its contention that the utilized manufacturing process may but does not necessarily result in the redistribution of particles. In response, Applicants respectfully submit that it is the words of the claim that define the invention,

and Claim 46 clearly recites that less particulate is disposed at the outer surface than in the interior of the membrane.

Accordingly, Sugiyama et al. do not expressly or inherently disclose a membrane in which less of the particulate is disposed at or near the outer surface than further in the interior of the membrane, nor would such a membrane be obvious from the teachings identified in the Sugiyama et al. patent.

Claim 66

Claim 66 is directed to a flexible composite sheet membrane, including a polymeric support, a first coating of a non-fiberized polymeric material, including a particulate blended with and randomly dispersed within the polymer. The particulate is substantially physically immobilized by the polymer. The membrane further includes a permeable and porous skin on the outer surface of the membrane. The membrane is formed, in part, by introducing the support into a chamber, including the polymeric material. The chamber has a wide opening, a pair of converging walls terminating in a narrow passageway of a predetermined length and an exit gap through which the support is passed at the rate of approximately 1 to 4 feet per minute.

As set forth above relative to Claim 46, the final Office Action rejected Claim 66 under 35 USC 102(b) as anticipated by Sugiyama et al., for the same reasons as set forth relative to Claim 46, stating:

As to claim 66, as there is no statement within the instant specification that the utilized manufacturing process necessarily results in the redistribution of particles, claim 66 is rejected in the same manner as claim 46.

As set forth on pages 16-17 of the present application, the method of making a membrane as set forth in Claim 66 is believed to result in a membrane wherein less particulate is dispersed near the outer surface than is disposed further in the interior portions of the membrane. For the reasons discussed above which are reincorporated here, a membrane of this type is neither disclosed nor suggested by the cited references. For these reasons, Claim 66 should also be allowed.

(B) Whether Claims 56-59 and 61-62 are anticipated under 35 USC 102(e) by U.S. Patent No. 5,914,039 to Mahendran et al.

Independent Claim 56 is directed to a flexible, composite sheet membrane that includes a polymeric support having a first and second side. At least one of the sides includes a first coating of a non-fiberized polymeric material. The polymeric material includes a particulate blended with a polymer which substantially immobilizes the polymer. The membrane further includes a second coating of a hydrophilic agent.

The Examiner's grounds for his final rejection of Claims 56-59 and 61-62 for anticipation are set forth in the Office Action of July 31, 2001, on page 5, section 7:

Claims 56-59 and 61-62 are rejected under 35 USC 102(e) as being anticipated by Mahendran et al. (US 5,914,039). As to claim 56, '039 discloses a flexible, composite sheet membrane comprising: a polymeric sheet

support (column 6, lines 32-43) having a coating of alumina blended with PVDF, and further contains a coating of hydrophilizing polymer (see column 3, lines 54-58). '039 also discloses particle sizes (column 5, lines 45-51), as recited in instant claim 57; supports which are contoured or rippled (column 6, lines 40-43), as recited in instant claim 58-59); distributed particulate (see figures 3-4, as recited in instant claim 61; and PVDF (see above), as recited in instant claim 62.

More specifically, the Patent Office now contends that the subject matter of claim 56 is anticipated solely by the following underlined passage of Mahendran et al.:

The method for making the preferred embodiment of the tubular filtration membrane supported on braid comprises, (a) introducing a flexible tubular braid into a coating nozzle, and into a rounding orifice therein, (b) dispersing α -Al particles in a solution of PVDF and adding a hydrophilic polymer in the presence of acid to yield a grafted polymer in a dope having a viscosity sufficient to provide a coating on a support, (c) extruding the dope on to the support at a rate sufficient to form a continuous layer of dope, (d) maintaining a longitudinal and axial tension on the braid sufficient to advance it through the nozzle, and (e) coagulating the dope to form a semipermeable film of polymer adherently secured to the tubular braid. (Col. 3, lines 52-64).

Applicants respectfully submit that Mahendran et al. do not anticipate the claimed membrane. Mahendran et al. disclose a filtration membrane made from polyvinylidene difluoride (PVDF) polymer with a limited amount of calcined α -alumina particles. The filtration membrane of Mahendran et al. further includes a hydrophilic compound that is added to the polymer PVDF/ α -alumina complex.

Although the α -alumina particles are described as being dispersed throughout the membrane, the membrane is formed by

chemically reacting the α -alumina particles with the polymer and the hydrophilic agent. This is unlike the claimed membrane as recited in Claim 56 where the particulate material is physically held by and immobilized by the polymer without the need for a separate chemical reaction. For this reason alone, the membrane of Claim 56 is not anticipated by Mahendran et al.

Furthermore, as indicated above, the hydrophilic agent is reacted with the α -alumina particles in a solution of PVDF in the presence of acid to yield a grafted polymer (see col. 3, lines 54-58 relied upon by Examiner). Elsewhere it is stated that the polyvinyl alcohol (the hydrophilic polymer) "reacts with the complex imparting hydrophilicity to the polymer (See Abstract).

Thus, it is apparent that the hydrophilic agent is initially combined with the PVDF and alumina particles, and that the combination is subjected to a chemical reaction. This resulting membrane is unlike the membrane of Claim 56 which is not produced by such a chemical reaction and includes a first coating of a particulate blended with polymer wherein the particles are substantially physically immobilized by the polymer and (2) a second coating of a hydrophilizing agent. Contrary to the Examiner's position, the passages of Mahendran et al. relied upon by the Examiner simply do not disclose a separate second coating of the hydrophilizing agent. For this additional reason, Mahendran et al. do not anticipate Claim 56.

(C) Whether Claims 56-59 and 61-65 are obvious under 35 USC 103(a) over the above-identified Sugiyama et al. in view of U.S. Patent No. 4,384,954 to Nakashima et al.

The Examiner's grounds for his final rejection of Claims 56-59 and 61-65 are set forth on page 6, section 9 of the Office Action, where it is stated that:

"Claims 51, 56-59 and 61-65 are rejected under 35 USC 103(a) as being unpatentable over Sugiyama et al. (US 4,728,432) in view of Nakashima et al. (US 4,384,954).

As to claim 51, '432 is expanded with respect to depended[sic] on claim 46 above. Claim 51 recites the additional limitation of a coating of a hydrophilic agent. '954, which is cited within '432, teaches the optional use of a hydrophilic coating treatment for improving the biocompatibility of an adsorbent material -- see columns 3-4. Maintaining biocompatibility is clearly a concern of '432 --see column 4, lines 1-4. It would have been obvious to one having ordinary skill in the art at the same time the invention was made to utilize the hydrophilic treatment of '954 in conjunction with the adsorbent system of '432 for the purpose of ensuring product safety by imparting biocompatibility characteristics.

Claims [sic] 56 is broader than claim 51 above, and is similarly rendered obvious.

The limitations of claims 57-59 and 61-65 are also disclosed by the '432 reference-- see the 35 USC 102 rejection above."

Applicants respectfully, submit that it would not have been obvious for one to combine Nakashima et al. with Sugiyama et al. for the simple reason that Nakashima et al. have nothing to do with sheet membranes and, for that matter, membranes generally. Nakashima et al. disclose only a column for blood protein

absorption. The main body of the column has a blood inlet port and blood outlet port. The ports are provided with filters and between the filters, there is packed a porous material, " (Col. 5, lines 59-62) .

Although both Sugiyama et al. and Nakashima et al. are concerned with removal of components from biological fluids, beyond this end use, the polymeric membrane of Sugiyama et al. and the packed column of Nakashima et al. have little in common. In fact, one of the benefits of the present invention is the ability to adsorb compounds while minimizing particle shedding. Minimization of particle shedding is achieved by immobilizing the particulate in a polymer. One interested in making a composite membrane and minimizing particle shedding would have little, if any, reason to even consider Nakashima et al. where there is no talk of immobilizing the particles.

In that regard, Applicants respectfully submit that Nakashima et al. is not within the present field of endeavor. That the porous material in Nakashima et al. may be coated with a hydrophilic polymer does not suggest that a composite membrane should include a second coating of a hydrophilizing agent as for example, recited in Claim 56. Accordingly, there would have been no motivation for one of skill to consider the proposed combination of Sugiyama et al. with Nakashima et al. For these reasons, Applicants submit new Claims 51, 56-59 and 61-65 would not have been obvious in view of the cited art.

Conclusion

For the reasons set forth above, Applicants respectfully submit that the new Claims 46-66 are now allowable and the decision of the Examiner rejecting these claims should be reversed.

Respectfully submitted,



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(9) APPENDIX

46. A flexible, composite sheet membrane comprising:

a flat sheet polymeric support, said support having a first side and a second side, wherein each of said first and second sides comprises a coating of a non-fiberized polymeric material,

said material comprising a particulate blended with a polymer, said particulate being substantially physically immobilized by said polymer,

each of said sides having a coating of said material substantially equal in thickness and wherein the outer surface of said membrane has a porous and selectively permeable skin, and wherein less of said particulate is disposed near said skin than is disposed further in the interior of said membrane.

47. The membrane of Claim 46 wherein the majority of said particles have a diameter less than about 20 μm .

48. The membrane of Claim 46 wherein said membrane comprises a contoured sheet.

49. The membrane of Claim 48 wherein said membrane comprises a rippled sheet.

50. The membrane of Claim 48 wherein said membrane comprises a pleated sheet.

51. The membrane of claim 46 further comprising a coating of hydrophilizing agent.

52. The membrane of Claim 46 wherein said polymer is selected from the group consisting of polyurethane, polyvinylidenefluoride, cellulose acetate; polyvinyl chloride and ethylene vinyl alcohol copolymer.

53. The membrane of Claim 46 comprising between about 5% and 30% of said polymeric material.

54. The membrane of Claim 46 comprising about 70% by weight of said particulate material.

55. The membrane of Claim 46 wherein said support comprises a polyester mesh material.

56. A flexible, composite sheet membrane comprising:
a flat sheet polymeric support, said support comprising a first side and a second side,
at least one of said first or second sides comprising a first coating of a particulate blended with a polymer, said particulate being substantially physically immobilized by said polymer, and
a second coating of a hydrophilizing agent.

57. The membrane of Claim 56 wherein the majority of said particles have a diameter less than about 20 μm .

58. The membrane of Claim 56 wherein said membrane comprises a contoured sheet.

59. The membrane of Claim 58 wherein said membrane comprises a rippled sheet.

60. The membrane of Claim 58 wherein said membrane comprises a pleated sheet.

61. The membrane of Claim 56 wherein less of said particulate is disposed near said skin than is disposed further in the interior of said membrane.

62. The membrane of Claim 56 wherein said polymer is selected from the group consisting of polyurethane, polyvinylidenefluoride, cellulose acetate, polyvinyl chloride and ethylene vinyl alcohol copolymer.

63. The membrane of Claim 56 comprising between about 5% and 30% of said polymeric material.

64. The membrane of Claim 56 comprising about 70% by weight of said particulate material.

65. The membrane of Claim 56 wherein said support comprises a polyester mesh material.

66. A flexible, composite sheet membrane comprising:
a flat sheet polymeric support,
a first coating of a non-fiberized polymeric material, said material comprising a particulate blended with a polymer, said particulate being substantially physically immobilized by said polymer, and

a selectively permeable and porous skin on the outer surface of said membrane, said membrane formed, in part, by:

introducing said support into a chamber including said polymeric material, said chamber having a wide opening, a pair of converging walls terminating in a narrow passageway of a predetermined length and an exit gap, and

passing said support through said chamber at the rate of approximately 1-4 ft/min.